TRIAMCINOLONE ACETONIDE LOTION, USP
0.1% Rx only

DESCRIPTION
The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. The steroids in this class include triamcinolone acetonide. Triamcinolone acetonide is designated chemically as 9-Fluoro-11,16a,17,21-tetrahydroxyprogna-1,4-diene-3,20-dione cyclic 16,17-aceetyl with acetonide. Graphic formula:

Each mL of 0.1% triamcinolone acetonide lotion provides 1 mg triamcinolone acetonide in a lotion base containing cetyl alcohol, citric acid, polysorbate 20, propylene glycol, purified water, simethicone 30% emulsion, sorbitan monoleate in a lotion base containing cetyl alcohol.

CLINICAL PHARMACOLOGY
Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics
The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epithelial barrier, and the long-acting nature of the corticosteroid. Systemic absorption of topical corticosteroids is low and represents an insignificant route of administration for systemic therapy. The percutaneous absorption of corticosteroids in normal intact skin is approximately 0.01% to 0.001% of a given dose when applied to the skin in a single range of concentrations (1% to 0.005%). Topical corticosteroids are not absorbed appreciably through intact skin and under occlusive dressings. Vasoconstrictor assays indicate that topical corticosteroids do not significantly decrease cutaneous blood flow at concentrations which produce therapeutic responses. Absorption at intact skin is reduced by factors such as: the integrity of the skin, the concentration of the compound, the thickness of the preparation, and the use of occlusive dressings. Application to broken skin or under occlusive dressings substantially increases percutaneous absorption. Absorption and penetration of topical corticosteroids may be influenced by such factors as dermal thickness, tissue hydration, and skin temperature. Administration of topical corticosteroids to children should be limited to the treatment of certain dermatoses for which systemic therapy is generally not warranted.

Occlusive Dressing Technique
Apply the 0.1% triamcinolone acetonide lotion to the affected area two to three times daily. Rub gently in. Reapplication is essential at each dressing change. If needed, additional lotion should be applied, without occlusion, during the day. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician. Occlusive dressings (reactions are listed in an approximate decreasing order of occurrence): burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, erythema, and miliaria.

INDICATIONS AND USAGE
Triamcinolone acetonide lotion 0.1% is indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS
Topical corticosteroids are contraindicated in those patients with a history of sensitivity to any of the components of the preparations.

PRECAUTIONS
General
Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifested by adrenal insufficiency in some patients. Adrenal and sexual steroid functions may also be suppressed at higher doses and for long periods of time. Symptoms of hypoadrenalinism and hypogonadism have been observed in some patients treated with systemic corticosteroids. When high doses of powerful topical corticosteroids have been administered, some patients have experienced signs and symptoms of hypercorticism (Cushing’s syndrome). These may include increased appetite, weight gain, fluid retention, muscle weakness, easy bruising, osteoporosis, diabetes, and impaired glucose tolerance. Treatment should not exceed 14 days except under special circumstances which require medical supervision and the use of low potency steroids. The use of topical corticosteroids in children is not recommended except under special circumstances which require medical supervision and the use of potent or very potent corticosteroids. Absorption from the skin at normal potency is generally not sufficient to produce detectable quantities in the blood. HPA axis suppression and adrenocortical insufficiency may also result from the use of high potency topical corticosteroids under occlusive dressings. The potential predisposing factors for such reactions should be considered when systemic therapy is indicated. In these situations, it may be necessary to gradually decrease the dosage of systemic corticosteroids while increasing the dose of topical corticosteroids. HPA axis suppression and adrenal insufficiency have been reported with the use of topical corticosteroids. If suppression of the HPA axis occurs, symptomatic manifestations may include nausea, vomiting, anorexia, periods of depression, hypotension, and achy muscles. The symptoms usually reverse upon discontinuation of the drug. Infrequently, signs and symptoms of Cushing’s syndrome may occur when potent topical corticosteroids are used for prolonged periods on large areas of the body. Citric acid serves as a buffer and should not be omitted. Optimum results are obtained when the skin is cleansed with water prior to application of the medication. The skin should then be dried and the medication applied. Application under occlusive dressings is contraindicated. An adequate therapeutic response may be delayed until the skin is dry.

Pediatric Use
Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS, General).

DOSEAGE AND ADMINISTRATION
Apply the 0.1% triamcinolone acetonide lotion to the affected area two to three times daily. Rub gently in. Reapply is essential at each dressing change. If needed, additional lotion should be applied, without occlusion, during the day. The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician. Occlusive dressings (reactions are listed in an approximate decreasing order of occurrence): burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and milia.

OVERDOSAGE
Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS, General).

ADVERSE REACTIONS
The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings (reactions are listed in an approximate decreasing order of occurrence): burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of skin, secondary infection, skin atrophy, striae, and milia.

Pediatric Use
Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see PRECAUTIONS, General).

DOSEAGE AND ADMINISTRATION
Apply the 0.1% triamcinolone acetonide lotion to the affected area two to three times daily. Rub gently in. Reapplication is essential at each dressing change. If needed, additional lotion should be applied, without occlusion, during the day. Reapplication is essential at each dressing change. If an infection develops, the use of occlusive dressings should be discontinued and appropriate antimicrobial therapy instituted.

HOW SUPPLIED
Triamcinolone Acetonide Lotion, USP 0.1%: plastic squeeze bottles containing 60 mL of lotion.

Storage
Store at 20–25°C (68–77°F) [see USP Controlled Room Temperature]. Avoid freezing.

Manufactured for:
QUALITEEST PHARMACEUTICALS
Huntsville, AL 35811

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